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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,820	06/01/2000	Thomas J. Mercolono	CDS-221	4698

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/585,820

Applicant(s)
MERCOLINO et al.

Examiner
James L. Grun, Ph.D.

Art Unit
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 Apr 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 20, 22, 23, and 25-51 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 20, 22, 23, and 25-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2002 has been entered.

Claims 29-51 are newly added. Claims 1-15, 17-19, 21, and 24 have been cancelled. Claims 16, 20, 22, 23, and 25-51 remain in the case.

Applicant is now required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Claims 16, 20, 22, 23, and 25-51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 16, 20, 29, 22, 23, and 49 positively claim identical subject matter as claimed in claims 25, 26, 30, 27, 28, and 50, respectively, and differ only in the intended use recitations of their preambles, recitations which do not serve to distinguish the same subject matter from itself. In these claims it is not clear what is encompassed or excluded by “in a single test” because a single test may be a multi-vessel technology.

In claims 25-28, 30, and 50, it is not clear what is being determined because the relationship of the cell populations to reverse ABO typing is not clear as reverse ABO typing is accepted as determining antibodies not cell populations.

In claims 31-35 and 51, it is not clear what is being determined because the relationships of antibody testing to the cell populations and to reverse ABO type are not clear. In these claims it is not clear what is encompassed or excluded by “in a single test” because a single test may be a multi-vessel technology.

In claims 36-41 the interrelationships of the steps and components are not clear, for example because: the relationship of antibody to sample or admixture is not clear; the relationship of antibody to first or second antigen or to agglutinate is not clear; the relationship of screen to detecting and identifying is not clear. In these claims it is not clear what is encompassed or excluded by “in a single test” because a single test may be a multi-vessel technology.

In claims 42-45, “the populations” and “the antibody” lack antecedent basis.

In claims 46-48, recitation of “the populations” lacks antecedent basis.

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Claims 42-44 and 46-47 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277) for reasons of record in the prior rejection of the similar subject matter of claims 8-11.

As set forth, Ullman teaches fluorescently labelled anti-blood group antigen antibodies and fluorescently labelled erythrocytes having blood group antigens thereon added simultaneously or sequentially to a sample of whole blood for multiparameter analysis of ABO blood type and isoantibodies (i.e. reverse blood typing) (see e.g. col. 3-4). A variety of combinations of parameters and suitable reagents are taught (see e.g. col. 3, Table 1). Suitable fluorescent labels are taught (e.g. col. 8-9). The reagents of the reference clearly anticipate those as instantly claimed.

Claims 16, 20, 22, 25-27, 29-34, 36-40, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al (U.S. Pat. No. 5,338,689) for reasons of record in the prior rejection of the similar subject matter of claims 16, 20, 22, and 25-27. The examiner notes that “a single test” as instantly claimed may be a multi-vessel technology.

Claims 16, 20, 22, 25-27, 29-34, 36-40, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al (U.S. Pat. No. 5,552,064) for reasons of record in the prior rejection of the similar subject matter of claims 16, 20, 22, and 25-27. The examiner notes that “a single test” as instantly claimed may be a multi-vessel technology.

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Claims 16, 20, 22, 23, and 25-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al (U.S. Pat. No. 5,552,064) in view of Shen et al (U.S. Pat. No. 5,594,808) for reasons of record in the prior rejection of the similar subject matter of claims 16, 20, 22, 23, and 25-28.

Applicant's arguments filed 22 April 2002 have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that the references of Yves [Lapierre] et al (U.S. Pat. No. 5,338,689), alone, or Chachowski et al (U.S. Pat. No. 5,552,064), alone or as modified, fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e.: erythrocytes stained with a dye to alter the color of one cell population; two distinct cell populations agglutinating in a single reaction vessel) are not recited in the claim(s) rejected over these references. Applicant's attention is again drawn to the vague recitation of "in a single test" noted previously in this Office action. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The disclosure of Ullman (U.S. Pat. No. 4,713,348) is essentially identical to the disclosure of Ullman (U.S. Pat. No. 4,584,277).

Vorpahl et al (U.S. Pat. No. 5,071,774) teach that determination of the agglutination of two sets of red blood cells can be used for determination of the presence of an agglutinating agent for one or both of the red blood cell sets (see e.g. col. 9). As in Ullman (U.S. Pat. No. 4,584,277), combined addition of means for separately agglutinating two sets of red blood cells (e.g., anti-blood group antigen antibodies) along with the two sets of erythrocytes (e.g. erythrocytes having blood group antigens thereon), at least one of the sets being labelled with a fluorophore such that the sets are separately detectable and distinguishable, to a sample is used in the method.

Chang et al (U.S. Pat. No. 4,748,129) teach the addition of a fluorescent agent capable of incorporation into a cell as a means of labelling erythrocytes for agglutination assays. Suitable fluorescent agents are taught (e.g. col. 4-7).

Vyas et al (U.S. Pat. No. 5,776,711) teach a simultaneous blood typing/antibody screening method using flow cytometry.

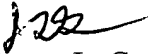
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.


James L. Grun, Ph.D.
June 14, 2002


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1808/641